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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,089	10/28/2003	Wing Y. Cheung	15039-2	4436

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EXAMINER	
KAPUSHOC, STEPHEN THOMAS	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,089	CHEUNG ET AL.	
	Examiner	Art Unit	
	Stephen Kapushoc	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) 6-11 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5 is/are rejected.

7)☒ Claim(s) 3 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 28 October 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/12/04, 10/28/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to methods to assay plants based on gene mutations, classified in class 435, subclass 6.

II. Claims 6-11, drawn to nucleic acids, classified in class 536, subclass 23.1.

Requirement for further restriction applicable to all groups

If applicant elects the invention of group I, applicant shall further select a single particular *Brassica* species from the group consisting of *B. napus*, *B. camepstris/rapa*, and *B. juncea*, as required by claim 3. Claim 3 will only be examined to the extent that it requires the select single particular *Brassica* species.

If applicant elects the invention of group II, applicant shall further select a single particular oligonucleotide sequence from the group consisting of SEQ ID NOs 5-88, 90-96. Only claims that require the selected single SEQ ID NO will be examined. For example, if applicant elects the invention of group II, and applicant further selects SEQ ID NO: 77, then claim 8 will be examined. Only a single SEQ ID NO will be examined.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process

for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the oligonucleotides of the invention of group II could be used for methods other than determining the presence of a mutation. For example, the oligonucleotides could be used for PCR amplification of nucleic acids for an expression vector, or as capture probes to isolate nucleic acids from a native source.

3. Regarding the requirement for further restriction among the different *Brassica* species of claim 3, each species is patentably distinct because they contain unique genomes of different nucleic acid sequences which may require different methods of nucleic acid analysis, at least in the form of different nucleic acid probes specific for any particular species. Additionally, a search of methods of genetic analysis of one species would not necessarily be coextensive so as to include the other species, thus a reference against one would not necessarily be a reference against any other species.

4. Regarding the requirement for further restriction among the different oligonucleotides of the invention of group II, each oligonucleotide is patentably distinct as they are all structurally unique because they are composed of different nucleic acid sequences. Thus a reference against one SEQ ID NO would not necessarily be a reference against any other SEQ ID NO, making the search of the SEQ ID NOs non-coextensive. Furthermore, the claims of the invention of group II encompass 91 different sequences (SEQ ID NOs 5-88, 90-96). A search of all of these SEQ ID NOs would be a large burden on the searching resources of the Office.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I and II require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. During a telephone conversation with Patricia McDaniels on 01/06/2006 a provisional election was made without traverse to prosecute the invention of group I, claims 1-5, with a further selection of *B. napus* for claim 3. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 6-11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Requirement For Information Under 37 C.F.R. 1.105

7. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

8. The May 2001 issue of the magazine Germination makes reference to an agreement between BASF and the Saskatchewan Wheat Pool in which the Saskatchewan Wheat Pool develops herbicide-resistant canola under the Clearfield Production System. It is noted that the assignee of the invention of the instant application is BASF. The examiner request the following information regarding the agreement: do the mentioned herbicide-resistant canola varieties contain the PM1 and PM2 mutations, and if so does the development of the new varieties include nucleic acid based methods to detect the M1 and PM2 mutations.

9. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

Claim Objections

5. Claim 3 is objected to because it contains non-elected subject matter. The claims would require examination of the non-elected *Brassica* species *B. campestris /rapa* and *B. juncea*. Applicant is reminded that prior to allowance, amendment of the claims commensurate in scope with the election will be required. For the purpose of

this office action, the claims have been considered in view of the elected *Brassica napa* species.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beetham et al (2001) (WO 01/25460) in view of Rutledge et al (1991, as cited in the IDS), Hattori et al (1995, as cited in the IDS), and Sathasivan et al (1991).

12. Beetham et al teaches several aspects of imidazolinone resistant plants (p.3 lns.14-27; p.16 l.14 – p.17 l.10), and specifically mentions *B. napus*, relevant to claims 1-3 of the instant application. Beetham teaches that imidazolinone resistance can be conferred by mutations in AHAS (the abbreviation for acetohydroxy acid synthase, and also known as acetolactate synthase or ALS) genes, and particularly mentions two mutations: one mutation in AHAS1 and one mutation in AHAS3, indicating that the mutations are known as PM1 and PM2 respectively (p.3). The reference further teaches that plants may have either or both of the mutations, and that mutations in the two genes confer different levels of resistance to imidazolinone herbicides (p.16).

Beetham et al does not teach a method for the detection of the PM1 and PM2 mutations in *Brassica napus*.

Rutledge et al teaches the nucleic acid and deduced amino acid sequence of the *Brassica napus* AHAS1 and AHAS3 genes (Fig. 2A and 2C). The reference teaches that DNA was isolated from leaf nuclei, relevant to claim 1 step (a). The reference also teaches that imidazolinone herbicides act through inhibition of AHAS (p.39, left column, last paragraph), and further teaches that herbicide resistance in *B. napus* mutants results from two unlinked alleles, and that the effect of combining the alleles in a hybrid line is additive for imidazolinone resistance. The reference teaches that the imidazolinone resistance alleles correspond to AHAS1 and AHAS3 (p.39, left column, last paragraph), and concludes that the sequences of the AHAS genes provides the basic information essential for the analysis of *Brassica* mutants with resistance to herbicides that act on AHAS (p.39, right column, last paragraph).

Rutledge et al does not indicate the nature of the mutations in AHAS 1 (PM1) and AHAS3 (PM2) that confer resistance to imidazolinone.

Hattori et al teaches the analysis of the AHAS3 gene from imidazolinone-resistant mutant *B. napus* cells, relevant to claim 1 step (c) of the instant application. The reference teaches that the AHAS3 gene from the mutant cells was cloned and sequenced, and the sequence of the gene from the mutant was compared to the wild-type AHAS3 sequence (p.420, right column, l.28). Hattori teaches the identification of a single basepair change (G to T) in AHAS3 that predicts a tryptophan to leucine amino acid change (p.421, left column, last paragraph), and provides a comparative alignment of deduced amino acid sequences in the region of the AHAS3 mutation responsible for herbicide resistance (p.421 Fig. 2). Based on the alignment provided in Fig. 2, and the

sequence of the AHAS3 gene provided by Rutledge et al, it is evident that the G to T mutation taught by Hattori is equivalent to the PM2 mutation claimed in the instant application. Hattori concludes that the identified mutation site in the AHAS3 gene is involved in the binding of imidazolinone herbicides, and teaches that the recovery of the same mutation in tobacco and *B. napus*. Further relevant to claim 4 of the instant application, Hattori teaches the amplification of the AHAS1 gene from isolated genomic DNA prior to determining whether or not mutations are present.

Sathasivan et al teaches the analysis of an *A. thaliana* mutation in the acetolactate synthase gene (referred to within the reference as ALS, which is an art recognized synonym for AHAS). The reference teaches that the mutation provides the molecular basis for imidazolinone resistance in *A. thaliana* (p.1044 – Abstract). Sathasivan et al teaches the specific nature of the *A. thaliana* mutation responsible for herbicide resistance as a G to A single-point mutation at nucleotide 1958 of the coding sequence, which predicts a serine to asparagine substitution at amino acid 653 (p.1044, left column, last paragraph; Fig. 2; Table 1). The reference also provides an alignment indicating the conservation of the deduced amino acid residues in the acetolactate synthase gene near the mutation site conferring imidazolinone resistance (Fig. 3). Based on the alignment provided in Fig. 3, the teachings of Beetham et al that the PM1 mutation is in AHAS1, the sequence of the AHAS1 gene provided by Rutledge et al, and the fact that Hattori et al teaches a mutation in AHAS3, it is evident that *A. thaliana* G to A mutation taught by Sathasivan is equivalent to the PM1 mutation claimed in the instant application. The reference also teaches that similar mutations at corresponding

nucleotide positions of other acetolactate synthase genes can confer imidazolinone resistance (p.1049, left column, last paragraph). Further relevant to claim 5, Sathasivan et al teaches the analysis of the sequence of the acetolactate synthase gene using a chain termination method (p.1045 – Nucleic acid techniques; Fig. 2), which is a primer extension based method for sequencing that can detect single nucleotide polymorphisms.

It would have been prima facie obvious to one of skill in the art at the time the invention was made to have combined the information and methods provided in the cited references to have created the claimed invention of a method to assay for the presence or absence of the PM1 and PM2 mutations to determine the imidazolinone tolerance of a plant. One would have been motivated to develop such an assay to efficiently determine the relative level of herbicide resistance in a plant using molecular techniques. One would have had a reasonable expectation of success because the cited references teach both the general aspects of the properties responsible for imidazolinone resistance, as well as the specific molecular characteristics that confer imidazolinone herbicide resistance. Beetham et al teaches that mutations in *Brassica* that confer resistance to imidazolinone are the PM1 mutation in the AHAS1 gene and the PM2 mutation in the AHAS3 gene (p.3). Rutledge et al also teaches that the two alleles responsible for imidazolinone resistance in a *B. napus* mutant correspond to the AHAS1 and AHAS3 genes, and that the effect of combining the alleles in a hybrid line is additive for imidazolinone resistance (p.39, right column, last paragraph). Rutledge et al further teaches the nucleic acid sequences and deduced amino acid sequences of the

B. napus AHAS1 and AHAS3 genes (Fig. 2A and 2C). Hattori et al teaches the identification of a G to T (tryptophan to leucine) mutation in the *B. napus* AHAS3 gene responsible for imidazolinone resistance that is equivalent to the PM2 mutation of the instant application. Sathasivan et al teaches the identification of a G to A (serine to asparaginie) mutation in the *A. thaliana* ALS gene and provides an amino acid alignment indicating that this mutation is equivalent to the PM1 mutation of the instant application.

Thus, in view of the teachings of the prior art, the claimed invention is prima facie obvious.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-5 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-25 of copending Application No. 10/695,546 (Pub. No.: US 2004/0171027 A1). This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

15. The copending '546 application claims methods for assaying a *Brassica* plant for imidazolinone resistant comprising the steps of isolating genomic DNA from a plant and detecting the PM1 mutation in AHAS1 and the PM2 mutation in AHAS3. The claims of the copending application also encompass the amplification of the isolated DNA (relevant to claim 4 of the instant application), as well as methods to detect single nucleotide polymorphisms that utilize the extension of primers (relevant to claim 5 of the instant application). Although the copending '546 application cites different nucleotide positions (paragraphs [0028]-[0029]) of the G to A mutation in AHAS1 and the G to T mutation in AHAS3, which are PM1 and PM2 respectively, it is evident from a comparative alignment of the gene sequences in the copending applications that the identical mutations at the equivalent positions are claimed.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other

copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

No claim is free of the art, no claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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